

REMARKS

The non-final Office Action dated November 18, 2008 has been carefully considered. Claims 1-19, 23, 25 and 26 are pending.¹ Claims 1 and 26 have been amended. Specifically, claim 1 has been amended to recite that an impermeable layer is disposed on the backing layer of the device, and a drug-in-matrix layer is disposed on the impermeable layer. Support for this amendment can be found in the originally-filed specification at, *e.g.*, page 7, lines 22-24. Claim 26 has been amended to recite that the drug layer is a drug-in-adhesive layer. Therefore, no new matter has been added.

Reconsideration and allowance of the present application in view of the above amendments and the following remarks are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

A. Claims 1-5, 7-19, 23, 25 and 26 Are Patentable Over Pagedas In View of Cleary

The Examiner has rejected claims 1-5, 7-19, 23, 25 and 26 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,221,384 to Pagedas ("Pagedas") in view of U.S. Patent No. 5,006,342 to Cleary *et al.* ("Cleary"). Specifically, the Examiner contends that in Pagedas, "the borders, as shown in figures 1-2 and 4-6, would have an adhesive layer, which are the same as the instant drawings" (Office Action, page 7). For the following reasons, Applicant disagrees.

Claim 1 recites a method of delivering a drug through a patient's skin using a transdermal delivery system comprising a plurality of patch units. Each patch unit comprises a backing layer having one or more borders, an impermeable layer disposed on the backing layer, a drug-in-matrix layer disposed on the impermeable layer, and an adhesive layer. At least a portion of the *adhesive layer is disposed on the borders of the backing layer, which is free of any drugs* (emphasis added). The plurality of patch units are connected to each other along one or more

¹ Applicant submits that claim 28, which is currently indicated as withdrawn, should be examined with pending claims 1-19, 23, 25 and 26. In the Restriction Requirement mailed September 18, 2006, the Examiner requested that Applicant elect one of the four listed groups. In response, Applicant elect without prejudice group II (claim 25), drawn to a method of delivering buprenorphine. The Examiner also indicated that claims 1-23 and 26 link groups II and I (drawn to a method of delivering fentanyl). Claim 28 depends from claim 26 and further recites that the narcotic analgesic of claim 26 is buprenorphine. Therefore, claim 28 is believed to correspond to the invention of group II. Accordingly, Applicant respectfully submits that claim 28 is improperly withdrawn.

borders of the patch units, and each patch unit is defined by one or more lines of separation along the borders of the patch units. The method includes the steps of separating at least one patch unit from the transdermal delivery system along at least one line of separation, and applying at least one patch unit such that the drug layer makes contact with the skin.

Claim 25 is directed to a method of delivering a drug through a patient's skin using a transdermal delivery system comprising a plurality of patch units. Each patch unit comprises a backing layer having one or more borders, a drug-in-matrix layer or a drug-in-adhesive layer comprising buprenorphine disposed on the backing layer, and an adhesive layer. At least a portion of *the adhesive layer is disposed on the borders of the backing layer, which is free of any drugs.*

Claim 26 is directed to a method of delivering a drug through a patient's skin using a transdermal delivery system comprising a plurality of patch units. Each patch unit comprises a backing layer having one or more borders, a drug-in-adhesive layer comprising a narcotic analgesic disposed on the backing layer, and an adhesive layer. At least a portion of *the adhesive layer is disposed on the borders of the backing layer, which is free of any drugs.*

Pagedas does not teach or suggest the method of delivering a drug wherein at least a portion of the adhesive layer is disposed on the drug-free borders of the backing layer of the patch unit, as recited in claims 1, 25 and 26, respectively. The Examiner contends that in Pagedas, since the membrane has a border around it consisting of the backing layer, and that since the drug is confined to the membrane, a person skilled in the art would determine that the border would comprise the adhesive material without drug admixed therein (Office Action, page 6). In response, Applicant submits that the border around the membrane shown in, e.g., Figures 1 and 2 of Pagedas, is not the border of the backing layer as presently claimed, but the border of layer 20, which, although referred to as the backing layer in Pagedas, is the equivalent of the release liner in the present application (*see col. 4, lines 1-2*).

With respect to the impermeable coating 28 in Pagedas (*i.e.*, the equivalent of the backing layer in the present claims), Applicant submits that Pagedas fails to teach or suggest the claim limitation that its borders are free of any drugs and covered by a portion of the adhesive layer. In fact, Pagedas teaches, and the Examiner acknowledges, that the adhesive may be over the entire surface of the membrane or may define an adhesive free area. This by no means suggests that

the adhesive would also be disposed upon the drug-free border of the impermeable coating (*i.e.*, the backing layer in the present claims). In fact, as discussed in the Response filed August 11, 2008, neither of Figures 3 and 3a even shows an adhesive disposed on the border of the impermeable coating, let alone disposed on the drug-free border of the impermeable coating. Thus, Pagedas is silent as to whether the adhesive is disposed upon a drug-free border of the impermeable coating.

Furthermore, with respect to claim 1, Pagedas fails to teach or suggest a patch unit comprising an impermeable layer disposed on the backing layer, upon which the drug-in-matrix layer is disposed. With respect to claim 25, Pagedas fails to teach or suggest, and the Examiner acknowledges, a drug layer comprising buprenorphine. With respect to claim 26, Pagedas fails to teach or suggest a patch unit comprising a drug-in-adhesive layer.

Cleary does not remedy the deficiencies of Pagedas. Cleary, unlike the presently claimed methods, does not teach or suggest a plurality of patch units wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, much less teach or suggest separating at least one patch unit from the transdermal delivery system along at least one line of separation. In addition, the transdermal delivery system in Cleary comprises a multiplicity of spaced structural lamina(s) and viscoelastic hydrophobic polymer lamina(s), upon which an adhesive lamina is disposed (Abstract). The drug is contained in the viscoelastic lamina(s), the adhesive lamina, or the structural lamina(s) (col. 2, lines 35-41 and 48-51; and col. 3, lines 67-68). This structure is considerably different from the structure disclosed in Pagedas. As such, Applicant submits that a person skilled in the art would not find any teaching, suggestion, motivation, or reasonable expectation of success to combine or modify the teachings of Pagedas and Cleary to arrive at the presently claimed method.

Moreover, the combination of Pagedas and Cleary would not result in the presently claimed methods. Cleary, like Pagedas, also fails to teach or suggest a patch unit wherein at least a portion of the adhesive layer is disposed on the drug-free borders of the backing layer. In fact, the transdermal delivery system in Cleary does not even have a distinct backing layer upon which a drug-in-matrix layer or drug-in-adhesive layer (claims 25 and 26) or an impermeable layer (upon which a drug-in-matrix layer is further disposed) (claim 1) is disposed, let alone such

a backing layer with drug-free borders with a portion of an adhesive layer disposed on the borders as presently claimed.

Therefore, claim 1 and its dependent claims, and claims 25 and 26, are believed to be patentable over Pagedas in view of Cleary. Thus, withdrawal of this rejection and allowance of claims 1-4, 7-19, 23, 25 and 26 are respectfully requested.

B. Claim 6 Is Patentable Over Pagedas In View Of Cleary And Further In View of Katz

Claims 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pagedas in view of Cleary and further in view of U.S. Patent No. 5,028,435 to Katz *et al.* ("Katz"). The Examiner acknowledges that Pagedas and Benecke [sic] do not teach the drug being encapsulated in microcapsules, but contends that Katz provides such disclosure.

Claim 6 depends from claim 1 and, as discussed above, is patentable over Pagedas and Cleary. Katz does not cure the deficiencies of Pagedas and Cleary. Katz, like Cleary, also fails to disclose or suggest a plurality of patch units wherein each patch unit is defined by one or more lines of separation along the borders of the patch units, much less a method of delivery a drug using such plurality of patch units as presently claimed.

Moreover, like Pagedas and Cleary, Katz does not teach or suggest a patch unit comprising an impermeable layer disposed between the backing layer and the drug-in-matrix layer, as recited in claim 1. Since claim 6 incorporates all the claim limitations of claim 1, claim 6 is believed to be patentable over Pagedas, Cleary, and Katz. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION


Thus, as the claim rejections are believed to be overcome, the pending claims are believed to be in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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